C. Remarks

The claims are 24-38, with claim 24 being the sole independent claim. Claim 39 has been cancelled without prejudice or disclaimer. Each of claims 24-38 have been amended to more clearly define Applicants' invention and to correct minor informalities. In addition, claim 24 has been amended to make clear that the solvent is water or an alcoholic solvent. Applicants submit that no new matter has been added by way of these amendments and that support is found throughout the application as filed (for example, on page 4, line 18 and page 11, line 22 to page 12, line 2). Reconsideration of the present claims is respectfully requested.

Claims 25-38 stand rejected under 35 U.S.C. §112, second paragraph. In view of Applicants' amendment of each of those claims to correct the dependencies thereof and well as to replace the phrase "free domperidone base" with --domperidone free base--, Applicants submit that the §112 rejection is now moot and should be withdrawn.

Claim 39 stands rejected under 35 U.S.C. §101 for statutory double patenting in view of claim 17 of U.S. Patent No. 6,726,928. In view of the cancellation of claim 39, Applicants submit that this rejection is now moot and should be withdrawn.

Claims 24-38 stand rejected for obviousness-type double patenting in view of claims 1, 2 and 4-16 of U.S. Patent No. 6,726,928. While Applicants respectfully traverse this rejection, in an effort to expedite prosecution of this case, it is Applicants' present intention to file a terminal disclaimer to overcome this rejection when all the other issues have been resolved.

Claims 24, 26-29, 31, 35, 37 and 38 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by *Ecanow* (U.S. Patent No. 5,382,437). Applicants respectfully traverse this rejection.

Ecanow relates to the preparation of a rapidly disintegrating oral dosage form of a drug by forming a solution of the drug in liquefied ammonia as a solvent together with gelatin, rigidifying with maltodextrin, and removing the ammonia to leave spaces in place of the frozen ammonia. By contrast, the present invention is directed to a process for the preparation of a solid, oral, rapidly disintegrating dosage form of a pharmaceutically active substance which has an unacceptable taste, said process involving the step of forming a solution or a suspension in a solvent that is either water or an alcoholic solvent. It is clear that *Ecanow* provides no teaching as to forming a solution or suspension using water or an alcoholic solvent. In fact, *Ecanow* goes so far as to state that "[n]o water or organic solvent need be used." *Ecanow*, col. 3, line 10.

For at least these reasons, Applicants submit that *Ecanow* does not anticipate claim 24 or its dependent claims and respectfully request withdrawal of the §102 rejection premised upon it.

Claims 24, 26-30, 32-34 and 36 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over *Gregory* (U.S. Patent No. 4,305,502) in view of *Ince* (U.S. Patent No. 4,657,929). Applicants respectfully traverse this rejection.

Gregory is directed to a process of forming shaped articles carrying pharmaceutical substances which disintegrate rapidly in water by subliming the solvent from a composition comprising the pharmaceutical substance and a solution of a carrier material in a solvent, the composition being in a solid state in one or more depressions in a sheet of filmic material, and then adhering a covering sheet around the depressions to

enclose the shaped articles in the depressions. See *Gregory*, col. 3, lines 57-68. However, *Gregory* does not address the problems associated with an active ingredient in a fast dissolving dosage form with an unacceptable taste. In fact, at column 1, lines 45-50, *Gregory* teaches that it is desirable to have the active ingredient be readily soluble. Hence, *Gregory* actually teaches away from the present invention. In addition, there is no teaching in *Gregory* about rendering the active substance less soluble. As such, it is respectfully submitted that claim 24 and its dependent claims are clearly distinguishable over *Gregory*.

The Examiner states that "[t]he method of formulation of a pharmaceutically active agent into a readily dissolving, orally administered tablet taught by Gregory et al. has the inherent property of rendering the active substance less soluble and more palatable. Therefore, it would be expected that an identical process, such as that taught by Gregory et al., would necessarily also render the active substance less soluble and more palatable." Office Action, pages 9-10. Applicants respectfully submit that the rejection fails to meet the requirements of a rejection based on inherency.

"In relying upon a theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." MPEP §2112 (quoting *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis added). Furthermore, to establish inherency, the extrinsic evidence

> must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

MPEP §2112 (quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (emphasis added)). Applicants respectfully submit that *Gregory* does not expressly or inherently describe rendering the active substance less soluble and more palatable.

The Examiner's above-quoted statements do not provide a basis in fact and/or technical reasoning to support the determination that the allegedly inherent characteristics of claim 24 necessarily flow from the teachings of the applied art. As such, the Examiner does not include a clear showing that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill, as required by MPEP §2112.

Therefore, Applicants respectfully request that (1) a basis in fact and/or technical reasoning be provided to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of *Gregory* itself, and (2) a showing that the extrinsic evidence makes clear that the missing descriptive matter is necessarily present in *Gregory*.

Ince does not remedy the deficiencies of *Gregory*. *Ince* is directed to pharmaceutical compounds that are 4-hydroxy phenethylamines. Domperidone is mentioned as one of the several examples of compounds that may be mixed with the active compound. However, *Ince* does not address the problems associated with an active ingredient in a fast dissolving dosage form with an unacceptable taste. *Ince* is relied upon as a teaching that the active compound may be mixed with an additional compound, such as domperidone. Beyond that, *Ince* is irrelevant so far as the presently claimed invention is concerned.

In sum, neither *Ince* or *Gregory* or the combination thereof renders the present invention obvious. What is more, given the above-noted deficiency in the Examiner's inherency argument, Applicants respectfully submit that no *prima facie* case of obviousness has been established. Simply put, the cited prior art fails to disclose or suggest certain key features of the present invention, namely the formulation of an active ingredient with an unacceptable taste in a fast dissolving dosage form and the rendering of the active substance less soluble. For at least these reasons, Applicants submit that *Gregory* and *Ince* do not render obvious claim 24 or its dependent claims and respectfully request withdrawal of the §103 rejection.

In view of the foregoing amendments and remarks, Applicants respectfully request favorable reconsideration and allowance of the claims in the present application.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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